NOVEN PHARMACEUTICALS INC
Form 10-Q
August 10, 2001

1

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

Quarterly Report Under Section 13 or 15 (d) of the
Securities Exchange Act of 1934

For the quarterly period ended June 30, 2001

Commission file number 0-17254

NOVEN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

| STATE OF DELAWARE | 59-2767632 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |

| 11960 S.W. 144TH STREET, MIAMI, FL | 33186 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

(305) 253-5099

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ].

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the last practicable date.

| CLASS | OUTSTANDING AT JULY 31, 2001 |
|---|---|
| Common stock $.0001 par value | 22,425,451 |

2

NOVEN PHARMACEUTICALS, INC.

INDEX





PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

NOVEN PHARMACEUTICALS, INC.

Condensed Statements of Operations
Three and Six Months Ended June 30,
(in thousands, except per share amounts)
(unaudited)

| | THREE MONTHS | | SIX MONT |
|---|---|---|---|
| | 2001 | 2000 | 2001 |
| Revenues: | | | |
| Product sales | $11,842 | $10,335 | $23,864 |
| License revenue | 752 | 146 | 1,419 |
| Total revenues | 12,594 | 10.481 | 25,283 |
| Expenses: | | | |
| Cost of products sold | 5,894 | 4,512 | 10,710 |
| Research and development | 2,410 | 3,555 | 4,637 |
| Marketing, general and administrative | 3,176 | 2,307 | 5,836 |
| Total expenses | 11,480 | 10,374 | 21,183 |
| Income from operations | 1,114 | 107 | 4,100 |
| Equity in earnings of Novogyne | 3,137 | 3,253 | 3,732 |
| Interest income, net | 482 | 267 | 1,101 |
| Income before income taxes | 4,733 | 3,627 | 8,933 |
| Provision for income taxes | 1,510 | 153 | 3,043 |
| Net income | $ 3,223 | $ 3,474 | $ 5,890 |
| Basic earnings per share | $ 0.14 | $ 0.16 | $ 0.26 |
| Diluted earnings per share | $ 0.14 | $ 0.15 | $ 0.25 |
| Weighted average number of common shares outstanding: | | | |
| Basic | 22,335 | 21,797 | 22,286 |
| Diluted | 23,561 | 22,895 | 23,585 |

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE STATEMENTS.

Condensed Balance Sheets
(in thousands, except share data)
(unaudited)

| | JUNE 30, 2001 | DE |
|---|---|---|
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 42,060 | |
| Accounts receivable (less allowance for doubtful accounts of $97 in 2001 and $121 in 2000) | 4,996 | |
| Due from Novogyne | 34,790 | |
| Inventories | 5,614 | |
| Net deferred income tax asset | 4,800 | |
| Prepaid and other current assets | 442 | |
| | 92,702 | |
| Property, plant and equipment, net | 15,963 | |
| Other Assets: | | |
| Investment in Novogyne | 21,763 | |
| Net deferred income tax asset | 10,345 | |
| Patent development costs, net | 1,993 | |
| Deposits and other assets | 1,209 | |
| | $ 143,975 | |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | $ 4,125 | |
| Notes payable - current portion | 256 | |
| Due to Aventis Pharmaceuticals | 30,000 | |
| Accrued compensation and related liabilities | 1,995 | |
| Other accrued liabilities | 3,482 | |
| Deferred license revenue - current portion | 3,011 | |
| | 42,869 | |
| Long-Term Liabilities: | | |
| Notes payable | 182 | |
| Deferred license revenue | 26,290 | |
| | 69,341 | |
| Commitments and contingencies | | |
| Stockholders' Equity: | | |
| Preferred stock - authorized 100,000 shares of $.01 par value; no shares issued or outstanding | -- | |
| Common stock - authorized 80,000,000 shares, par value $.0001 per share; issued and outstanding 22,402,588 shares at June 30, 2001 and 22,177,598 at December 31, 2000 | 2 | |
| Additional paid-in capital | 76,331 | |
| Accumulated deficit | (1,699) | |
| | 74,634 | |
| | $ 143,975 | |

=========

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE STATEMENTS.





NOVEN PHARMACEUTICALS, INC.

Condensed Statements of Cash Flows
Six Months Ended June 30,
(in thousands)
(unaudited)

| | 2001 |
|---|---|
| Cash flows from operating activities: | |
| Net income | $ 5,89 |
| Adjustments to reconcile net income to net cash provided by operating activities: | |
| Depreciation and amortization | 73 |
| Amortization of patent costs | 10 |
| Deferred income tax provision | 41 |
| Recognition of deferred license revenue | (1,41 |
| Equity in earnings of Novogyne | (3,73 |
| Decrease (increase) in accounts receivable | 68 |
| (Increase) decrease in due from Novogyne | (1,87 |
| Decrease (increase) in inventories | 48 |
| Decrease in prepaid and other current assets | 5 |
| (Increase) decrease in deposits and other assets | (1,09 |
| (Decrease) increase in accounts payable | (2,39 |
| (Decrease) increase in accrued compensation and related liabilities | (50 |
| Increase (decrease) in other accrued liabilities | 2,28 |
| Increase in deferred license revenue | 3,50 |
| Cash flows provided by operating activities | 3,12 |
| Cash flows from investing activities: | |
| Purchase of property, plant and equipment, net | (1,54 |
| Investment in Novogyne | (15,68 |
| Distribution from Novogyne | 13,08 |
| Payments for patent development costs | (13 |
| Cash flows (used in) provided by investing activities | (4,27 |
| Cash flows from financing activities: | |
| Issuance of common stock | 2,40 |
| Payments on notes payable | (16 |
| Cash flows provided by financing activities | 2,23 |
| Net increase in cash and cash equivalents | 1,08 |

| | |
|---|---|
| Cash and cash equivalents, beginning of period | 40,97 |
| Cash and cash equivalents, end of period | $ 42,06 |

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE STATEMENTS.





NOVEN PHARMACEUTICALS, INC.

NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

1. Basis of Presentation:

In management's opinion, the accompanying unaudited condensed financial statements of Noven Pharmaceuticals, Inc. ("Noven") contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the financial position of Noven as of June 30, 2001, and the results of its operations for the three and six months ended June 30, 2001 and 2000. The results of operations and cash flows for the six months ended June 30, 2001 are not necessarily indicative of the results of operations or cash flows which may be reported for the remainder of 2001.

The accompanying unaudited condensed financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission for reporting on Form 10-Q. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. The unaudited condensed financial statements should be read in conjunction with the financial statements and the notes to the financial statements included in Noven's Annual Report on Form 10-K for the year ended December 31, 2000.

The accounting policies followed for interim financial reporting are the same as those disclosed in Note 1 of the notes to the financial statements included in Noven's Annual Report on Form 10-K for the year ended December 31, 2000.

Noven and Novartis Pharmaceuticals Corporation ("Novartis") entered into a joint venture, Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) ("Novogyne"), effective May 1, 1998, to market and sell women's healthcare products in the United States and Canada. These products include Noven's transdermal estrogen delivery systems marketed under the brand names Vivelle(R) and Vivelle-Dot(TM) and, effective March 30, 2001, Noven's transdermal combination estrogen/progestin delivery system marketed under the brand name Combipatch(TM). Noven accounts for its 49% investment in Novogyne under the equity method and reports its share of Novogyne's earnings as "Equity in earnings of Novogyne" on its Statements of Operations. Noven defers the recognition of 49% of its profit on products sold to Novogyne until the products are sold by Novogyne.

2. Inventories:

The following are the major classes of inventories (in thousands):

| | JUNE 30, 2001 | DECEMBER 31, 2000 |
|---|---|---|
| Finished goods | $ 135 | $ 319 |
| Work in process | 1,882 | 1,567 |
| Raw materials | 3,597 | 4,212 |
| Total | $5,614 | $6,098 |



7

3. Income Taxes:

Noven accounts for income taxes in accordance with the provisions of Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes". Provisions for income taxes for the three and six months ended June 30, 2001 are based on the Federal statutory and state income tax rates. Provisions for income taxes for the three and six months ended June 30, 2000 reflect provisions for the Federal alternative minimum tax and state income taxes.

4. Cash Flow Information:

Cash payments for income taxes were $0.9 million in 2001 and $0.3 million in 2000. Cash payments for interest were $21,000 in 2001 and $35,000 in 2000.

In connection with the Combipatch(TM) transaction described in Note 5 below, in March 2001, Noven recorded a $40 million receivable from Novogyne and a $40 million payable to Aventis Pharmaceuticals, the United States pharmaceuticals business of Aventis Pharma AG ("Aventis"). In June 2001, Novogyne paid the first $10 million installment to Aventis.

Accrued compensation and related liabilities for the year ended December 31, 1999 included bonuses for employees and officers of $0.8 million that were settled by issuance of 55,000 shares of common stock during the quarter ended March 31, 2000.

Noven recorded a $1.1 million income tax benefit to additional paid-in capital for the six months ended June 30, 2001 derived from the exercise of non-qualified stock options and disqualifying dispositions of incentive stock options.

5. License Agreements:

On March 30, 2001, Novogyne acquired the exclusive United States marketing rights to Combipatch(TM) (estradiol/norethindrone acetate transdermal system) in a series of transactions involving Novogyne, Noven, Novartis and Aventis. Prior to the transaction, Aventis had been Noven's exclusive licensee for Combipatch(TM) in the United States. The transaction was structured as (a) a direct purchase by Novogyne from

Aventis of certain assets for $25 million, which was paid at closing, (b) a grant-back by Aventis to Noven of certain intellectual property rights relating to Combipatch(TM), and (c) a simultaneous license by Noven to Novogyne of these intellectual property rights. The consideration payable by Noven to Aventis, and by Novogyne to Noven, is $40 million, due in four quarterly installments of $10 million each, payable beginning June 1, 2001. Novogyne agreed to indemnify Noven against Noven's obligation to Aventis. The first $10 million quarterly installment was paid by Novogyne to Aventis on June 1, 2001. As a consequence of the transaction and under the terms of Noven's existing license agreement with Aventis, Noven received $3.5 million from Aventis, which amount was deferred and recognized as license revenue over ten years beginning in the first quarter of 2001.

In a related transaction, Novartis Pharma AG ("Novartis AG") acquired from Aventis the development and marketing rights to future generations of Noven's combination estrogen/progestin patch in all markets other than Japan, and Novogyne expects to sublicense the United States rights to these product improvements. If and when any future generation combination products are commercialized, Novogyne will pay a





royalty to Novartis AG on the United States sales of such products. Noven will manufacture Combipatch(TM) and any future combination products and will supply such products to Novogyne and to Novartis AG. In June 2001, Noven and Novartis entered into a development agreement relating to future generations of combination estrogen/progestin patch products.

6. Investment in Novogyne:

Noven shares in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of $6.1 million to Novartis. Novogyne produced sufficient income in the first quarters of 2000 and 2001 to meet Novartis' annual preferred return and for Noven to recognize earnings from Novogyne under the formula. Noven's share of Novogyne's earnings increases as Novogyne's product sales increase, subject to a cap of 49%.

During the three and six months ended June 30, 2001 and 2000, Noven had the following transactions with Novogyne (in thousands):

| | THREE MONTHS | | SIX MONTHS | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | 2000 |
| Revenue: | | | | |
| Trade product | $ 2,842 | $ 3,202 | $ 4,086 | $ 7,637 |
| Sample product and other | 1,559 | 801 | 1,577 | 1,544 |
| Royalty | 950 | 904 | 1,766 | 1,696 |
| | $ 5,351 | $ 4,907 | $ 7,429 | $10,877 |
| Reimbursed Expenses: | | | | |

| | | | | |
|---|---|---|---|---|
| Services | $ 4,000 | $ 2,392 | $ 6,954 | $ 4,536 |
| Product specific marketing | 1,214 | 942 | 1,839 | 1,325 |
| | $ 5,214 | $ 3,334 | $ 8,793 | $ 5,861 |

As of June 30, 2001 and December 31, 2000, Noven had amounts due from Novogyne of $34.8 million and $2.9 million, respectively, representing $30 million related to the license of Combipatch(TM) (see Note 5) for 2001 and the balance representing amounts due for products sold to and marketing expenses reimbursable by Novogyne.

The unaudited condensed Statements of Operations of Novogyne for the three and six months ended June 30, 2001 and 2000 are as follows (in thousands):

| | THREE MONTHS | | SIX MONTHS | |
|---|---|---|---|---|
| | 2001 | 2000 | 2001 | |
| Revenues | $20,852 | $15,840 | $34,720 | $ |
| Cost of sales | 3,887 | 2,598 | 6,074 | |
| Selling, general and administrative expenses | 8,323 | 5,316 | 13,122 | |
| Amortization of intangible assets | 1,541 | -- | 1,541 | |
| Income from operations | 7,101 | 7,926 | 13,983 | |
| Interest income | 64 | 286 | 623 | |
| Net income | $ 7,165 | $ 8,212 | $14,606 | $ |



9

Subject to the approval of Novogyne's management committee, cash may be distributed to Novartis and Noven based upon a contractual formula. For the three and six months ended June 30, 2001, Noven received distributions of $2.9 million and $13.1 million, respectively, from Novogyne based on the results of operations for the year ended December 31, 2000 and the five months ended May 31, 2001. For the six months ended June 30, 2000, Noven received a cash distribution of $2.2 million from Novogyne based upon the results of operations for the year ended December 31, 1999. These amounts were recorded as reductions in the investment in Novogyne when received.

In connection with the Combipatch(TM) transaction described in Note 5 above, for the three and six months ended June 30, 2001, Noven contributed $3.4 million and $15.7 million, respectively, to Novogyne. These amounts were recorded as increases in the investment in Novogyne when paid.

7. Recent Accounting Pronouncements:

In June 2001, the Financial Accounting Standards Board approved the issuance of SFAS No. 141, "Business Combinations", and SFAS No. 142, "Goodwill and Other Intangible Assets". These standards, which were issued in July 2001, establish accounting and reporting for business combinations. SFAS No. 141 requires all business combinations entered into subsequent to June 30, 2001 to be accounted for using the purchase method of accounting. SFAS No. 142 provides that goodwill and other intangible assets with indefinite lives will not be amortized, but will be tested for impairment on an annual basis. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001; however, early adoption is permitted. Noven does not expect the adoption of these statements to have a material effect on its financial statements or disclosures.

8. Other:

In September 2000, Noven entered into a Severance and Non-Competition Agreement with Steven Sablotsky, Co-Chairman of its Board of Directors. Pursuant to the agreement, Mr. Sablotsky's employment as an officer of Noven terminated on June 1, 2001. Noven paid Mr. Sablotsky $1.2 million on that date, which is being amortized over the period of his three-year non-competition agreement. In July 2001, Mr. Sablotsky resigned as a director of Noven.

In June 2001, Noven's stockholders approved an increase in the number of authorized common shares from 40 million to 80 million.



ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the financial statements, the related notes and management's discussion and analysis of financial condition and results of operations included in Noven's Annual Report on Form 10-K for the year ended December 31, 2000 and the financial statements and related notes included in Item 1 of this Quarterly Report on Form 10-Q. Except for historical information contained herein, the matters discussed in this report are "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about Noven's plans, objectives, expectations, estimates, strategies, product approvals and development plans, and anticipated financial results. These statements are typically identified by the use of terms such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "should," "will," and similar words. These statements are based on Noven's current expectations and beliefs concerning future events but are subject to risks and uncertainties that could cause actual results to differ materially from those expressed therein. In addition to the important factors described in Noven's Annual Report on Form 10-K, the following important factors, among others, could cause Noven's actual results to differ materially from those expressed in any forward-looking statements: Noven's dependence on strategic alliances and its relationships with its licensees, risks associated with clinical trials and product development, including any future generations of Noven's combination estrogen/progestin patch, the recent shortfall in international product orders expected to be received from Novartis, the ability of Novogyne to generate sufficient operating income to service the obligations

owing to Aventis with respect to the Combipatch(TM) transaction, fluctuations in quarterly revenue and research and development expenses, the effect of changes in taxation, as well as economic, competitive, governmental and technological factors affecting Noven's operations, markets, products and prices. Noven does not undertake to update any of these forward-looking statements or to announce the results of any revisions to these forward-looking statements except as required by law.

Substantially all of Noven's product sales were to its licensees, Novogyne, Novartis AG and Aventis. Revenues from product sales are recognized at the time of shipment. Certain license agreements provide for an adjustment to the price of the product based upon the licensee's actual sales price. Noven records such adjustments to revenues at the time that the information necessary to make the determination is received from the licensees. Royalty revenue consists of royalties payable by Novogyne and Novartis from sales of Vivelle(R) and Vivelle-Dot(TM) in the United States and Canada. Royalty revenue is recognized when earned and determinable and is included in product sales.

License revenue consists of up-front, milestone and similar payments under license agreements and is recognized when earned under the terms of the applicable agreements. In most cases, license revenue will be deferred and recognized over time.

Certain license agreements entitle Noven to minimum fees. Noven records revenue related to minimum fees at the time that supporting data is provided by the licensee. If the minimum fees are not determinable, Noven records these fees on a cash basis. These fees are included in product revenue.

Revenues from product sales to licensees may fluctuate from quarter to quarter depending on various factors not in Noven's control, including but not limited to, the marketing efforts of each licensee, the inventory requirements





of each licensee, the impact of competitive products, the timing and scope of Estalis(R) and Estradot(TM) launches by Novartis AG, the product pricing of each licensee and the timing of certain royalty reconciliations and payments under Noven's license agreements.

Noven shares in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of $6.1 million to Novartis. In the first quarters of 2001 and 2000, Novartis' preferred return was satisfied. Noven reports its share of Novogyne's earnings as "Equity in earnings of Novogyne" on its Statements of Operations.

RESULTS OF OPERATIONS

SIX MONTHS ENDED JUNE 30, 2001 COMPARED TO SIX MONTHS ENDED JUNE 30, 2000

Total revenues for the six months ended June 30, 2001 were $25.3 million, an increase of $5.2 million, or 26%, over the same period in the prior year. The increase in revenues was primarily attributable to an increase in product sales of $4.1 million, or 21%, for the six months ended June 30, 2001 over the same period in the prior year. Product sales in the 2001 period included $1.4 million in minimum fee payments related to sales of Menorest(R) in certain European countries in 2000. The remaining $2.7 million of the increase in product sales was primarily attributable to higher sales of Estalis(R) outside of the United States and, to a lesser extent, sales of Combipatch(TM) in the United States. A decline in sales of Vivelle(R) and Vivelle-Dot(TM) to

Novogyne due to planned inventory reductions at Novogyne partially offset the increased sales of Noven's other products. License revenue increased $1.1 million, or 384%, primarily due to the amortization of license fees received in connection with the license of Estradot(TM) to Novartis AG in the fourth quarter of 2000 and the license of Combipatch(TM) to Novogyne in the first quarter of 2001. Product orders from Novartis AG for international markets have, to date, been substantially less than anticipated. Noven expects that the failure to receive these expected orders will significantly affect revenue for the second half of 2001 and that total revenues for the full year 2001 will be only modestly higher than the $42.9 million in total revenues reported for 2000.

Gross profit (product sales less cost of products sold) for the six months ended June 30, 2001 was $13.2 million (55% of product sales), compared to $10.8 million (54% of product sales) for the same period in the prior year. The increase in gross margin resulted from higher minimum fee payments and a decrease in the deferred profit related to sales of product to Novogyne. The decrease in deferred profit on sales to Novogyne resulted from a decline in Novogyne's inventory during the first six months of 2001. See Note 1 to Notes to Unaudited Condensed Financial Statements. The increase in gross margin was partially offset by an unfavorable product mix as Noven sold more product outside of the United States, while United States sales declined. Noven's foreign sales have a lower gross margin. Noven expects its gross margin percentage to be in the low 50 percent range for the full year 2001, primarily due to anticipated reductions in production volume in the second half of 2001 and to increased profit deferral related to expected sales of Combipatch(TM) to Novogyne.

Research and development expenses decreased approximately $0.7 million, or 14%, for the six months ended June 30, 2001 compared to the same period in the prior year. The decrease was attributable primarily to the completion of certain clinical studies for Noven's methylphenidate transdermal delivery system, partially offset by increases related to additional personnel and related costs. Noven expects an increase in research and development expenses in the remainder of 2001, primarily related to additional clinical studies associated with Noven's methylphenidate transdermal delivery system. The future level of research and development expenditures will depend on, among other



things, the status of products under development and the outcome of clinical trials, strategic decisions by management, the consummation of new license agreements and Noven's liquidity. Further, such expenses may vary significantly from quarter to quarter depending on product development cycles and the timing of clinical studies.

Marketing, general and administrative expenses increased approximately $1.4 million, or 33%, for the six months ended June 30, 2001 compared to the same period in the prior year. This increase was due primarily to higher outside consulting services related to the implementation of an enterprise resource planning system, consulting services related to improvements in production efficiency, and to higher legal fees related to the Combipatch(TM) transaction.

For the six months ended June 30, 2001 and 2000, Noven reported equity in earnings of Novogyne of $3.7 million. Novogyne's revenue increased from $29.1 million for the six months ended June 30, 2000 to $34.7 million in the comparable 2001 period. This increase was attributable to increased sales of Vivelle-Dot(TM) and Combipatch(TM) (licensed in March 2001), partially offset by decreased sales of Vivelle(R). Novogyne's selling, general and administrative expenses increased from $9.5 million for the six months ended June 30, 2000 to

$13.1 million in the comparable 2001 period, primarily due to expenses relating to the relaunch of the Combipatch(TM) product and to the expansion of the Novogyne sales force. Novogyne amortized $1.5 million related to the Combipatch(TM) acquisition cost during the six months ended June 30, 2001. For the first six months of 2001, Novogyne had net income of $14.6 million, compared to $15.5 million for the same period in the prior year.

Interest income, net increased approximately $0.6 million, or 136%, for the six months ended June 30, 2001 compared to the same period in the prior year, primarily due to higher average balances in cash and cash equivalents.

Noven's effective tax rate increased from 3.4% for the six months ended June 30, 2000 to 34.1% for the six months ended June 30, 2001. The provisions for income taxes for the six months ended June 30, 2001 are based on the Federal statutory and state income tax rates. The provisions for income taxes for the six months ended June 30, 2000 reflect provisions for the Federal alternative minimum tax and state income taxes. As of June 30, 2001, Noven had a net deferred tax asset of $15.1 million. Realization of this deferred tax asset depends upon Noven generating sufficient future taxable income. Although realization is not assured, management believes it is more likely than not that the deferred income tax asset will be realized based upon estimated future taxable income. Noven expects its effective tax rate to be between 34% and 36% for full year 2001.

Net income for the six months ended June 30, 2001 was $5.9 million ($0.25 diluted earnings per share), compared to $5.3 million ($0.23 diluted earnings per share) for the same period in the prior year. Noven expects that diluted earnings per share for the full year 2001 will be $.40 to $.45 per share.

THREE MONTHS ENDED JUNE 30, 2001 COMPARED TO THREE MONTHS ENDED JUNE 30, 2000

Total revenues for the three months ended June 30, 2001 were $12.6 million, an increase of $2.1 million, or 20%, over the same period in the prior year. The increase in revenues was primarily attributable to an increase in product sales of $1.5 million, or 15%, for the three months ended June 30, 2001 over the same period in the prior year. This increase in product sales was primarily attributable to higher sales of Combipatch(TM) in the United States and, to a lesser extent, sales of Estalis(R) outside of the United States. A decline in sales of Vivelle(R) and Vivelle-Dot(TM) to Novogyne partially offset



the increased sales of Noven's other products. License revenue increased $0.6 million, or 415%, primarily due to the amortization of license fees received in connection with the license of Estradot(TM) to Novartis AG in the fourth quarter of 2000 and the license of Combipatch(TM) to Novogyne in the first quarter of 2001.

Gross profit (product sales less cost of products sold) for the three months ended June 30, 2001 was $5.9 million (50% of product sales) compared to $5.8 million (56% of product sales) for the same period in the prior year. The decline in gross margin was attributable to product mix, as Noven sold more product outside of the United States, while United States sales remained flat. Noven's foreign sales have a lower gross margin.

Research and development expenses decreased approximately $1.1 million, or 32%, for the three months ended June 30, 2001 compared to the same period in the prior year, attributable primarily to the completion of certain clinical studies for Noven's methylphenidate transdermal delivery system.

Marketing, general and administrative expenses increased approximately $0.9 million, or 38%, for the three months ended June 30, 2001 compared to the same period in the prior year. This increase was primarily due to higher outside consulting services related to the implementation of an enterprise resource planning system and consulting services related to improvements in production efficiency.

For the three months ended June 30, 2001 and 2000, Noven reported equity in earnings of Novogyne of $3.1 million and $3.3 million, respectively. Novogyne's revenue increased from $15.8 million in the three months ended June 30, 2000 to $20.9 million in the comparable 2001 period. This increase was attributable to increased sales of Vivelle-Dot(TM) and Combipatch(TM) (licensed in March 2001), partially offset by decreased sales of Vivelle(R). Novogyne's selling, general and administrative expenses increased from $5.3 million for the three months ended June 30, 2000 to $8.3 million in the comparable 2001 period, primarily due to expenses relating to the relaunch of the the Combipatch(TM) product and to the expansion of the Novogyne sales force. Novogyne amortized $1.5 million related to the Combipatch(TM) acquisition cost during the three months ended June 30, 2001. For the three months ended June 30, 2001, Novogyne had net income of $7.2 million, compared to $8.2 million for the same period in the prior year.

Interest income, net increased approximately $0.2 million, or 80%, for the three months ended June 30, 2001 compared to the same period in the prior year, primarily due to higher average balances in cash and cash equivalents.

Noven's effective tax rate increased from 4.2% for the three months ended June 30, 2000 to 31.9% for the three months ended June 30, 2001. The provisions for income taxes for the three months ended June 30, 2001 are based on the Federal statutory and state income tax rates. In addition, net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes for the three months ended June 30, 2001. The provisions for income taxes for the three months ended June 30, 2000 reflect provisions for the Federal alternative minimum tax and state income taxes.

Net income for the three months ended June 30, 2001 was $3.2 million ($0.14 diluted earnings per share), compared to $3.5 million ($0.15 diluted earnings per share) for the same period in the prior year.





LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2001 and December 31, 2000, Noven had $42.1 million and $41.0 million, respectively, in cash and cash equivalents. Working capital increased by $3.1 million from $46.7 million at December 31, 2000 to $49.8 million at June 30, 2001.

Net cash of approximately $3.1 million was provided by operating activities during the first six months of 2001, compared to approximately $0.3 million provided by operating activities during the same period in the prior year. Net cash generated by operating activities primarily resulted from the receipt of a license fee in the amount of $3.5 million from Aventis in connection with the Combipatch(TM) license transaction. Changes in working capital and improved operating results accounted for most of the remaining

fluctuation.

Net cash of approximately $4.3 million was used in investing activities during the first six months of 2001, compared to approximately $1.6 million provided by investing activities during the same period of the prior year. During the six months ended June 30, 2001, Noven received distributions totaling $13.1 million from Novogyne. In connection with the Combipatch(TM) transaction, Noven contributed $15.7 million to Novogyne as its proportionate share of the payments to Aventis. During the six months ended June 30, 2001, Noven purchased $1.5 million in property, plant and equipment, net of which the most significant asset related to software for the enterprise resource system.

Net cash of approximately $2.2 million was provided by financing activities during the first six months of 2001, compared to approximately $1.6 million provided by financing activities during the same period of the prior year, primarily resulting from an increase in cash received from the issuance of common stock in connection with the exercise of stock options.

In December 2000, Noven entered into a secured revolving credit facility (the "Credit Facility") providing for borrowings of up to the lesser of $10 million or eligible accounts receivable. The Credit Facility will terminate in April 2002 and bears interest at LIBOR plus 1.50% (5.3% at June 30, 2001). At June 30, 2001, there were no amounts outstanding under the Credit Facility. Terms of the Credit Facility include, among other things, minimum net worth, revenue and operating results requirements, as well as compliance with certain financial ratios, measured on a quarterly basis.

Noven's principal sources of short-term liquidity are existing cash, cash generated from product sales, fees and royalties under license agreements and borrowings under its Credit Facility. In November 2000, Noven entered into an exclusive license agreement with Novartis AG relating to Estradot(TM), pursuant to which Noven received an up-front license payment of $20 million and will receive an additional milestone payment upon registration by Novartis AG of the licensed product in certain European countries. There can be no assurance that Novartis AG's registration efforts will be successful, and therefore there can be no assurance that Noven will receive the additional milestone payment.

Over the next year, Noven expects to invest up to $3 million in plant and equipment and software implementation costs to increase production capacity and to implement an enterprise resource planning system. Cash requirements for Federal and state income taxes are also expected to increase. Additionally, as part of the Combipatch(TM) transaction entered into in March 2001, the





consideration payable for certain intellectual property rights by Noven to Aventis, and by Novogyne to Noven, is $40 million, due in four quarterly installments of $10 million each, payable beginning June 1, 2001. Novogyne agreed to indemnify Noven against Noven's obligations to Aventis. The first $10 million quarterly installment was paid by Novogyne to Aventis on June 1, 2001. Noven expects that most of these installment payments will be funded from cash flows from Novogyne's operations. There can be no assurance that Novogyne will be able to generate sufficient income and cash flows from operations to meet these installment obligations. To the extent that Novogyne pays these obligations from cash generated by operations, the cash available for distribution to its members (including Noven) will be reduced correspondingly. If Novogyne's cash generated by operations is not sufficient to fund all or a portion of the remaining installments, Noven and Novartis may contribute additional capital to Novogyne. If Noven and Novartis elect not to contribute the necessary additional capital, Novogyne would be required to raise additional

funds in order to meet its obligations, whether through the incurrence of indebtedness or otherwise.

Noven believes that it will have sufficient cash available to meet its operating needs and anticipated short-term capital requirements, including any additional capital contributions to Novogyne. For the long term, Noven intends to utilize funds derived from the above sources, as well as funds generated through sales of products under development. Noven expects that such funds will be comprised of payments received pursuant to future licensing arrangements, as well as Noven's direct sales of its own products. Noven expects that its cash requirements will continue to increase, primarily to fund clinical studies for products under development and for plant and equipment to expand production capacity. There can be no assurance that Noven will successfully complete the development of such products, that Noven will obtain regulatory approval for any such products, that any approved product may be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that Noven will successfully negotiate future licensing arrangements. To the extent that capital requirements exceed available capital, Noven will seek alternative sources of financing to fund its operations. In addition to the Credit Facility, alternative financing may be needed to fund further activities. No assurance can be given that alternative financing will be available, if at all, in a timely manner, or on favorable terms. If Noven is unable to obtain satisfactory alternative financing, Noven may be required to delay or reduce its proposed expenditures, including expenditures for research and development and plant and equipment, in order to meet its future cash requirements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK.

Noven had no variable rate debt outstanding during the six months ended June 30, 2001. Therefore, changes in interest rates did not affect interest expense, earnings or cash flows in that period. Market risks relating to Noven's operations may result from changes in LIBOR interest rates if Noven borrows under its Credit Facility. Noven cannot predict market fluctuations in interest rates and their impact on any variable rate debt that Noven may have outstanding from time to time, nor can there be any assurance that fixed rate long-term debt will be available at favorable rates, if at all.



PART II. OTHER INFORMATION

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Annual Meeting of Stockholders held on June 5, 2001.

(i) Election of Directors

| | FOR | AGAINST |
|---|---|---|
| Sidney Braginsky | 19,076,966 | 103,709 |
| John G. Clarkson, M.D. | 18,944,326 | 236,349 |
| Lawrence J. DuBow | 19,081,811 | 98,864 |
| Regina E. Herzlinger | 19,081,536 | 99,139 |
| Steven Sablotsky | 14,899,321 | 4,281,354 |
| Robert C. Strauss | 14,886,662 | 4,294,013 |

(ii) The approval of an amendment to Noven's Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 40 million to 80 million was approved by an affirmative vote of 18,074,162 shares to a negative vote of 1,090,414 shares, with 16,099 shares abstaining.

(iii) The ratification of the appointment of Deloitte & Touche LLP as Noven's independent certified public accountants for 2001 was approved by an affirmative vote of 18,995,587 shares to a negative vote of 167,761 shares, with 17,327 shares abstaining.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) EXHIBITS

3.1 Certificate of Amendment of Certificate of Incorporation, dated June 5, 2001.

10.1 Development Agreement, dated June 1, 2001, between Novartis Pharma AG and Noven Pharmaceuticals, Inc.*

(b) REPORTS ON FORM 8-K

On April 4, 2001, Noven filed a Current Report on Form 8-K relating to the acquisition of Combipatch(TM) by Novogyne and the results of Noven's preliminary analysis of the Phase III clinical study for its transdermal methylphenidate product.

---

* Noven agrees to furnish a copy of the exhibits and schedules to this agreement to the Securities and Exchange Commission upon request.



SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NOVEN PHARMACEUTICALS, INC.

Date: AUGUST 10, 2001

By: /s/ JAMES B. MESSIRY

James B. Messiry
Vice President and
Chief Financial Officer